



(10) **Patent No.:** US 9,226,782 B2
(45) **Date of Patent:** *Jan. 5, 2016

CPC A61B 17/025; A61B 17/7083; A61B
17/0218; A61B 17/3417; A61B 17/3421;
A61B 2017/3443; A61B 2017/0256; A61B
2019/462; A61M 29/00; A61M 29/02
USPC 600/210, 204, 235, 203, 201;
606/246–256, 96, 190, 99, 90, 191,
606/279. 86 A. 914

See application file for complete search history.

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US 2013/0245382 A1 Sep. 19, 2013

(Continued)

Related U.S. Application Data

(63) Continuation of application No. 12/909,158, filed on Oct. 21, 2010, now Pat. No. 8,444,678, which is a continuation of application No. 10/914,983, filed on Aug. 10, 2004, now Pat. No. 7,824,410, which is a

Primary Examiner — Pedro Philogene

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(51) **Int. Cl.**
A61B 17/88 (2006.01)
A61B 1/32 (2006.01)

(Continued)

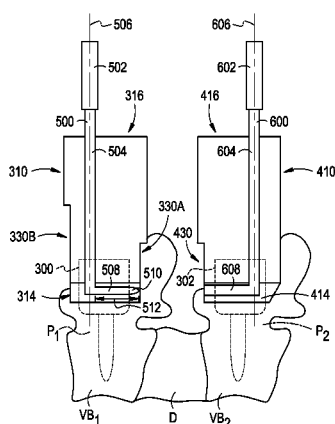
(52) **U.S. Cl.**
CPC *A61B 17/7083* (2013.01); *A61B 17/025*
(2013.01); *A61M 29/00* (2013.01);

(57) **ABSTRACT**

A system for minimally invasive spine surgery includes a plurality of bone anchors, a spinal rod, a plurality of dilators of differing lengths and diameters, and a surgical access port. The surgical access port includes a proximal end, a distal end, and a sidewall defining a lumen extending from the proximal end to the distal end. The port may include a first opening formed in the sidewall that defines a passageway for medical hardware from the lumen to external to the port. The system can include first instrument for creating a subcutaneous pathway from the opening in the port.

(Continued)

9 Claims, 7 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 10/021,809,
filed on Oct. 30, 2001, now Pat. No. 7,008,431, and a
continuation-in-part of application No. 10/024,221,
filed on Oct. 30, 2001, now Pat. No. 6,916,330.

(51) Int. Cl.

A61B 17/70 (2006.01)

A61M 29/00 (2006.01)

A61M 29/02 (2006.01)

A61B 17/02 (2006.01)

A61B 17/34 (2006.01)

A61B 19/00 (2006.01)

(52) U.S. Cl.

CPC **A61M 29/02** (2013.01); **A61B 17/0218**
(2013.01); **A61B 17/3417** (2013.01); **A61B**
17/3421 (2013.01); **A61B 2017/0256** (2013.01);
A61B 2017/3443 (2013.01); **A61B 2019/462**
(2013.01)

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FIG. 1

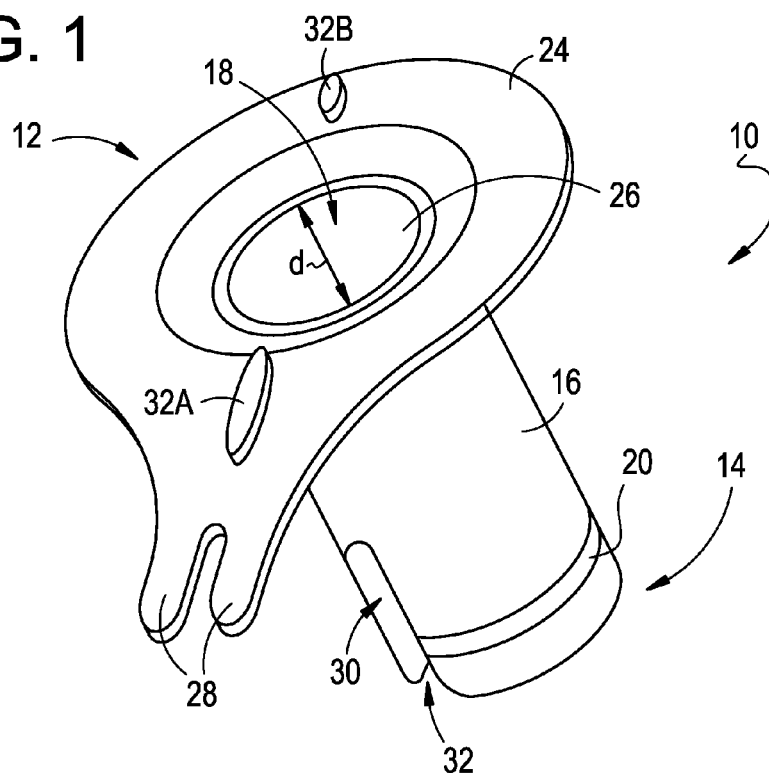


FIG. 2

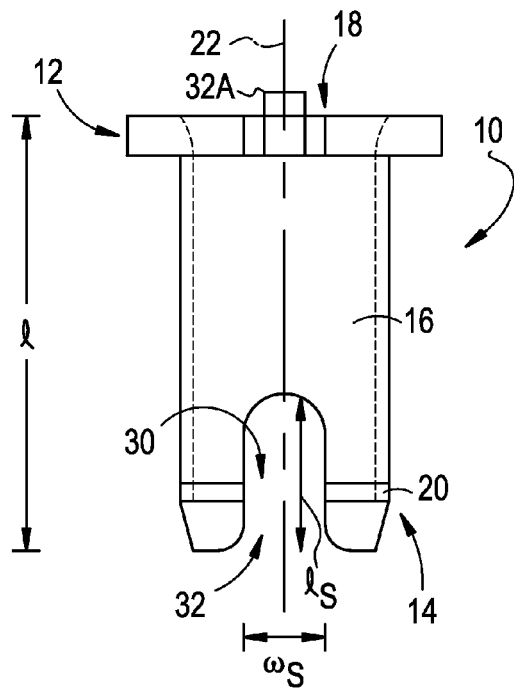


FIG. 3

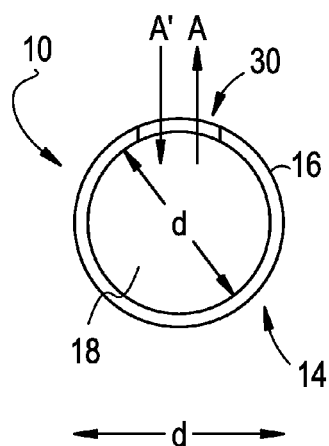


FIG. 4

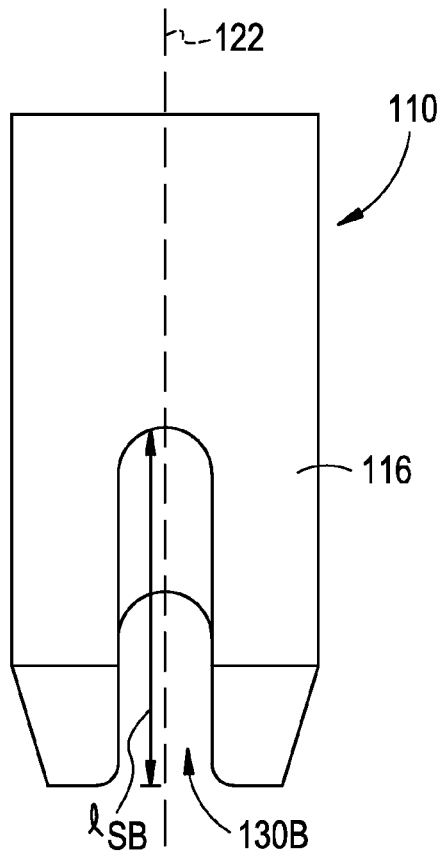


FIG. 5

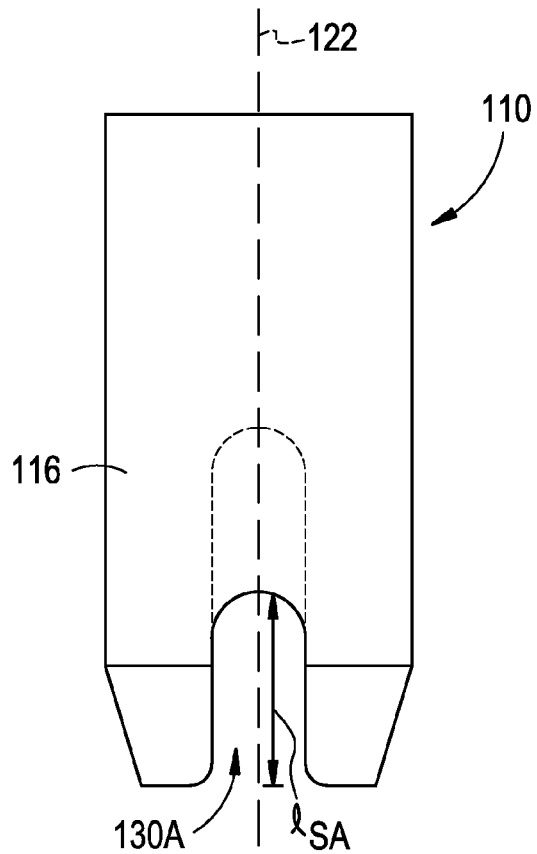


FIG. 6

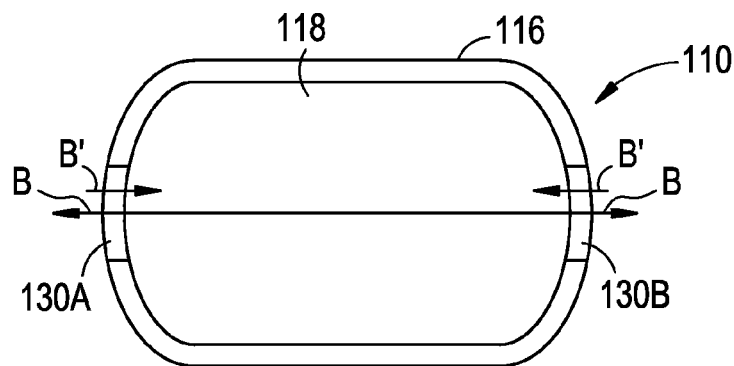


FIG. 7

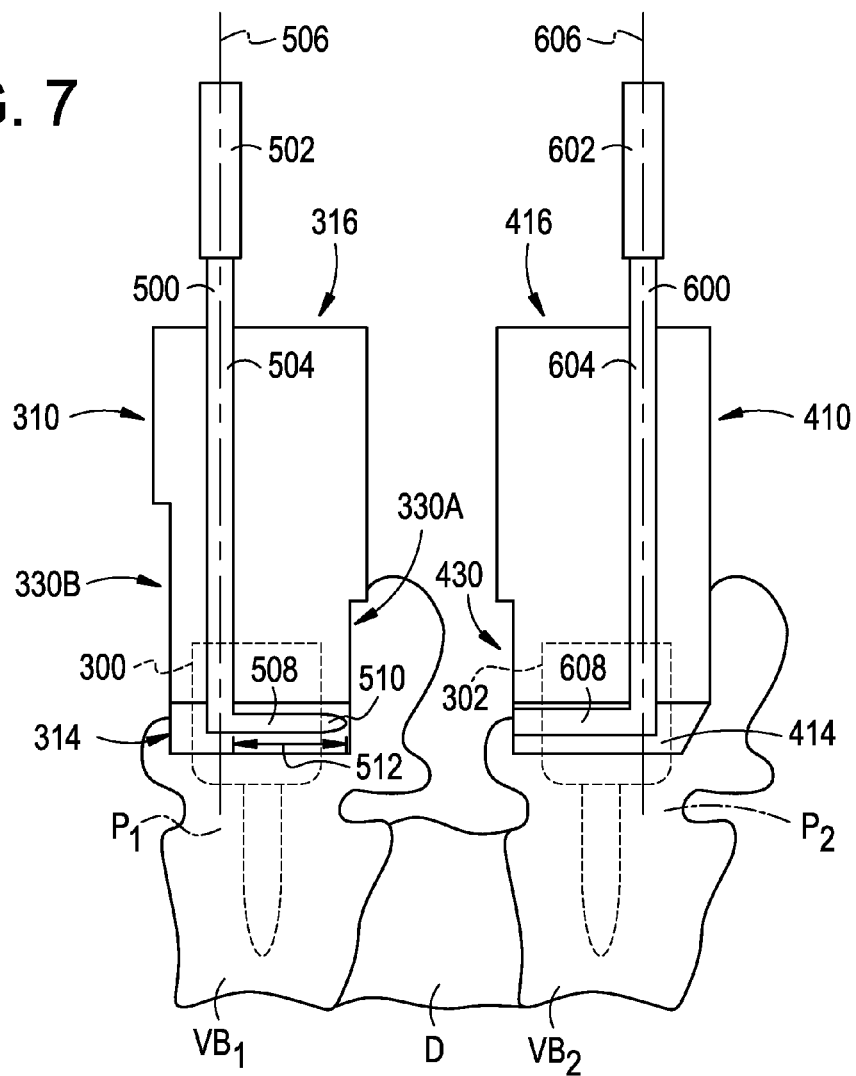


FIG. 8

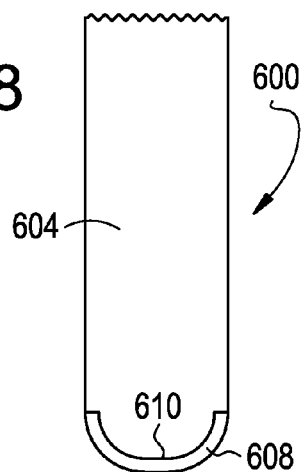
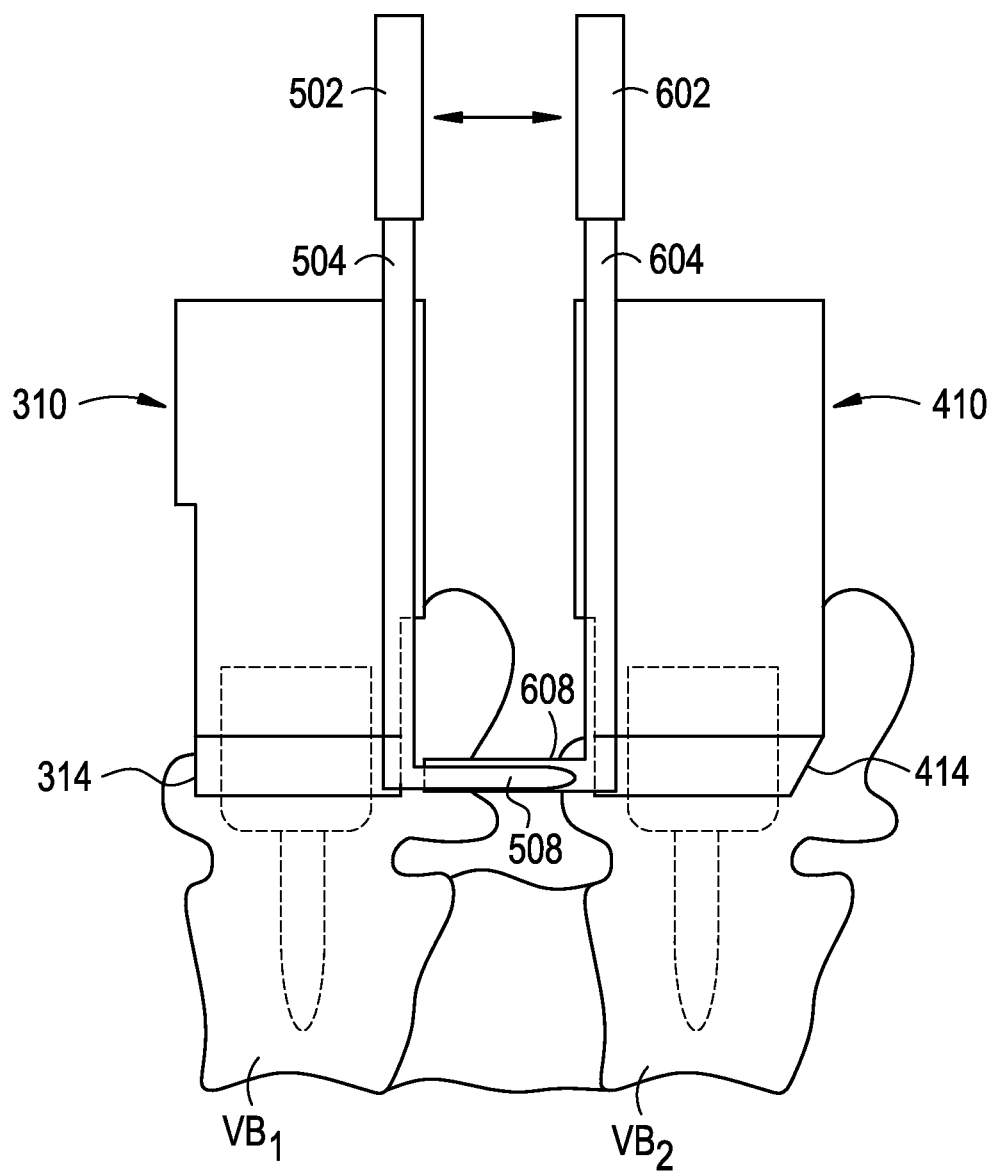


FIG. 9



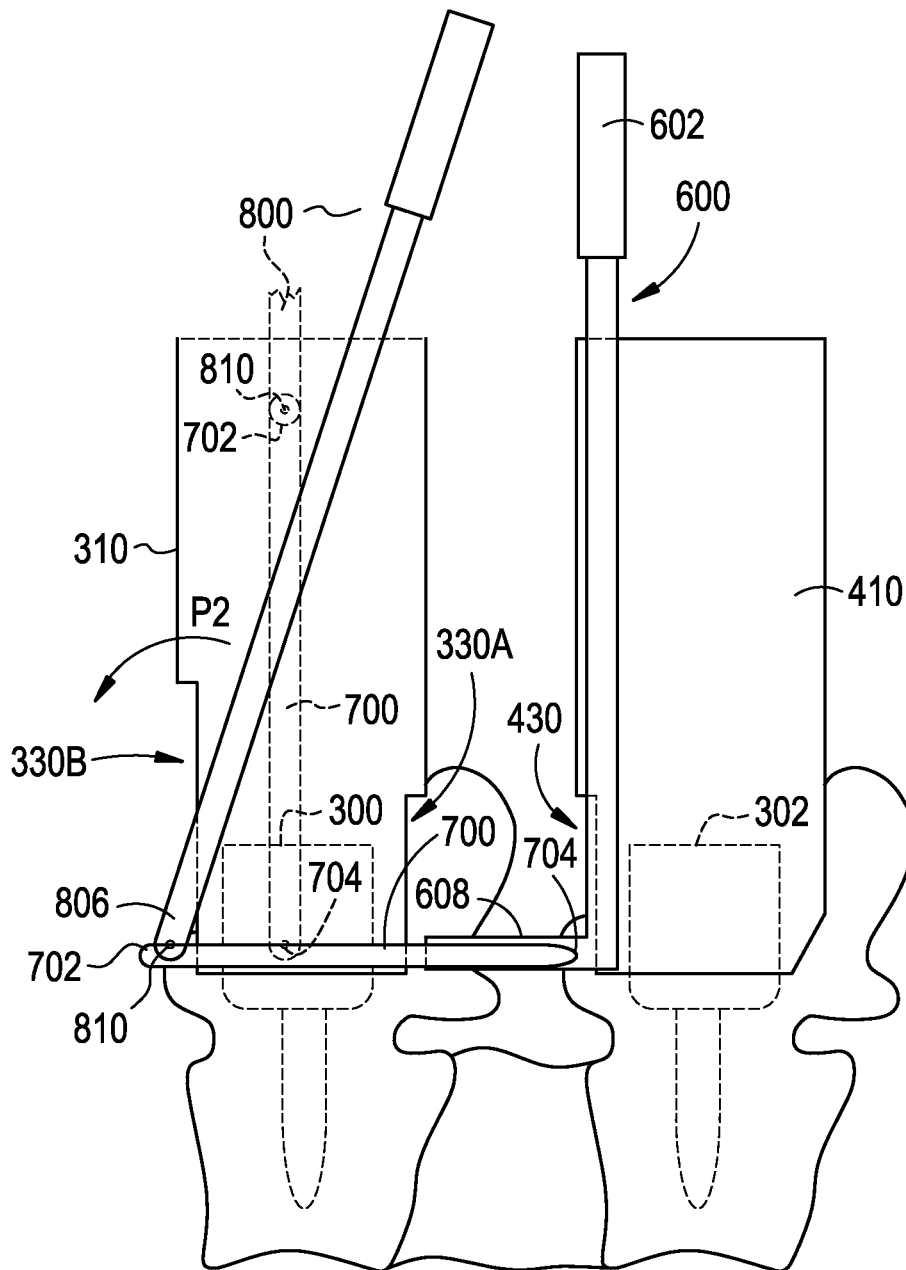


FIG. 11

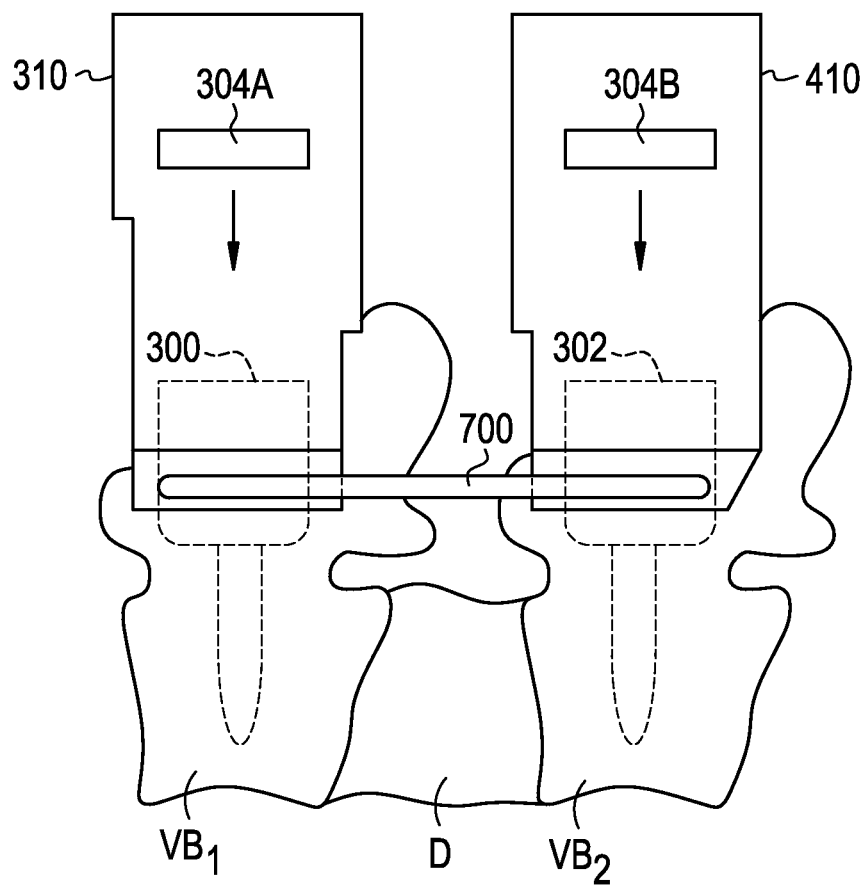


FIG. 12

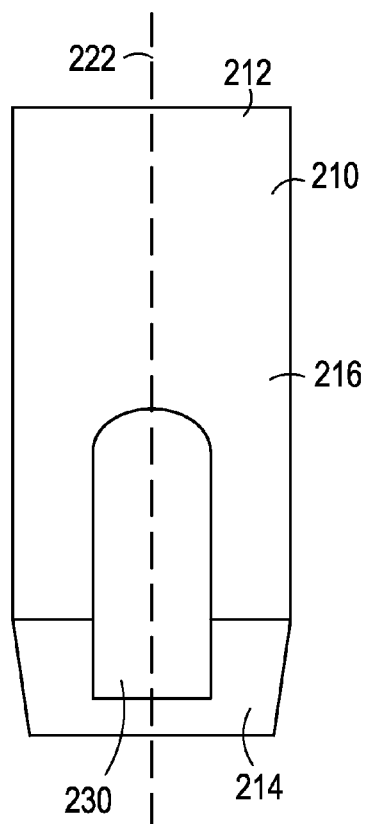
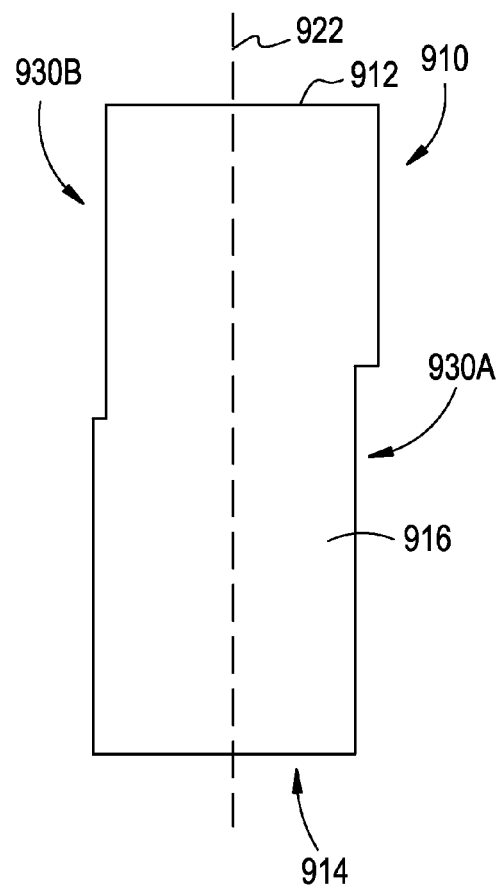


FIG. 13



1

INSTRUMENTS AND METHODS FOR MINIMALLY INVASIVE SPINE SURGERY

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/909,158, filed Oct. 21, 2010, which is a continuation of Ser. No. 10/914,983, filed Aug. 10, 2004, which is a continuation-in-part of U.S. patent application Ser. No. 10/021,809, filed Oct. 30, 2001, and is a continuation-in-part of U.S. patent application Ser. No. 10/024,221, filed Oct. 30, 2001. Each of the aforementioned patent applications is incorporated herein by reference.

BACKGROUND

For a number of known reasons, spinal fixation devices are used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies. Such devices typically include a spinal fixation element, such as a relatively rigid fixation rod or plate, that is coupled to adjacent vertebrae by attaching the element to various anchoring devices, such as hooks, bolts, wires, or screws. The fixation elements can have a predetermined contour that has been designed according to the properties of the target implantation site, and once installed, the fixation element holds the vertebrae in a desired spatial relationship, either until desired healing or spinal fusion has taken place, or for some longer period of time.

Spinal fixation elements can be anchored to specific portions of the vertebrae. A variety of anchoring devices have been developed to facilitate engagement of a particular portion of the bone. Pedicle screw assemblies, for example, have a shape and size that is configured to engage pedicle bone. Such screws typically include a threaded shank that is adapted to be threaded into a vertebra, and a head portion having a rod-receiving element, often in the form of a U-shaped recess formed in the head. A set-screw, plug, or similar type of closure mechanism is used to lock the fixation element, e.g., a spinal rod, into the rod-receiving head of the pedicle screw. In use, the shank portion of each screw is threaded into a vertebra, and once properly positioned, a rod is seated through the rod-receiving member of each screw and the rod is locked in place by tightening a cap or other closure mechanism to securely interconnect each screw and the fixation rod.

Recently, the trend in spinal surgery has been moving toward providing minimally invasive devices and methods for implanting bone anchors and spinal fixation devices. One such method, for example, is disclosed in U.S. Pat. No. 6,530,929 of Justis et al. and it utilizes two percutaneous access devices for implanting an anchoring device, such as a spinal screw, into adjacent vertebrae. A spinal rod is then introduced through a third incision a distance apart from the percutaneous access sites, and the rod is transversely moved into the rod-engaging portion of each spinal screw. The percutaneous access devices can then be used to apply closure mechanisms to the rod-engaging heads to lock the rod therein. While this procedure offers advantages over prior art invasive techniques, the transverse introduction of the rod can cause significant damage to surrounding tissue and muscle.

Accordingly, there remains a need for improved minimally invasive devices and methods for treatment of spinal disorders.

SUMMARY

Disclosed herein are instruments and methods that facilitate the treatment of spinal disorders in a minimally invasive

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manner. In particular, the disclosed methods permit the delivery and implanting of one or more bone anchors and/or one or more fixation elements, for example, a spinal rod, in a minimally invasive manner thereby limiting trauma to surrounding tissue. Moreover, certain exemplary methods disclosed herein facilitate the removal of diseased disc material and the placement of an interbody fusion device to promote spinal fusion, on one or both sides of the spine, in a minimally invasive manner. Also, disclosed herein are instruments that facilitate the subcutaneous delivery and connection of a fixation element, such as a spinal rod, to a bone anchor.

In one exemplary embodiment, an exemplary minimally invasive surgical method comprises making a first incision in a patient, positioning a first port in the first incision, advancing a distal end of the port into proximity to a vertebra, and positioning an instrument through an opening proximate the distal end of the port.

In one exemplary embodiment, an exemplary minimally invasive surgical method comprises inserting a first port that defines a first pathway to a first vertebra, advancing a first anchor through the first port to the first vertebra, inserting a second port that defines a second pathway to a second vertebra, advancing a second anchor through the second port to the second vertebra, positioning a first end of a fixation element in the first port, and advancing the first end of the fixation element subcutaneously through an opening in the first port and an opening in second port to the second anchor.

In one exemplary embodiment, an exemplary minimally invasive surgical method comprises making a first incision in a patient, positioning a first port in the first incision, advancing a first anchor through a first pathway defined by the first port to a first anchor site on the first vertebra, making a second incision in the patient, positioning a second port in the second incision, advancing a second anchor through a second pathway defined by the second port to a second anchor site on the second vertebra, positioning a first end of a fixation element in the first port, advancing the first end of the fixation element subcutaneously through an opening in the first port and an opening in second port to the second anchor, and coupling the fixation element to the first anchor and the second anchor.

In one exemplary embodiment, an exemplary surgical access port comprises a proximal end, a distal end spaced apart a distance from the proximal end and a sidewall defining a lumen extending from the proximal end to the distal end. In the exemplary port, the lumen has a length sufficient to at least span from a skin incision to proximate a vertebra. The exemplary port may include a first opening formed in the sidewall that defines a passageway for medical hardware from the lumen to external to the port.

In one exemplary embodiment, a system for minimally invasive spine surgery comprises a first dilator having a first diameter and a surgical access port. In the exemplary system, the port may comprise a proximal end, a distal end spaced apart a distance from the proximal end, and a sidewall defining a lumen extending from the proximal end to the distal end. In the exemplary system, the lumen of the port may have a length sufficient to at least span from a skin incision to proximate a vertebra and may have a diameter greater than the first diameter. The exemplary port may have a first opening formed in the sidewall that defines a passageway for medical hardware from the lumen to external to the port.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the methods and instruments disclosed herein will be more fully understood by reference to the following detailed description in

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conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate principles of the methods and instruments disclosed herein and, although not to scale, show relative dimensions.

FIG. 1 is a perspective view of an exemplary embodiment of a surgical access port, illustrating an opening formed in a sidewall of the port;

FIG. 2 is a side view of the surgical access port of FIG. 1;

FIG. 3 is a bottom view of the surgical access port of FIG. 1;

FIG. 4 is a front view of an exemplary embodiment of a surgical access port, illustrating a first opening formed in a sidewall of the port;

FIG. 5 is a rear view of the surgical access port of FIG. 4, illustrating a second opening formed in the sidewall of the port;

FIG. 6 is a bottom view of the surgical access port of FIG. 4;

FIG. 7 is a side view in cross section of a first surgical access port and a second surgical access, illustrating an instrument system comprising a first instrument and a second instrument positioned in the ports to facilitate creation of a subcutaneous pathway between the ports;

FIG. 8 is a front view of the second instrument of the instrument system illustrated in FIG. 7;

FIG. 9 is a side view in cross section of the ports of FIG. 7, illustrating the creation of a subcutaneous pathway between the ports;

FIG. 10 is a side view in cross section of the ports of FIG. 7, illustrating the placement of a spinal rod along the subcutaneous pathway between the ports and between bone anchors positioned in the ports;

FIG. 11 is a side view in cross section of the ports of FIG. 7, illustrating the spinal rod in position between the ports;

FIG. 12 is a front view of an exemplary embodiment of a surgical access port having an opening positioned between the distal end and the proximal end of the port; and

FIG. 13 is a side view of an exemplary embodiment of a surgical access port having a proximal opening and a distal opening.

DETAILED DESCRIPTION

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the instruments and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the instruments and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

The articles “a” and “an” are used herein to refer to one or to more than one (i.e. to at least one) of the grammatical object of the article. By way of example, “an element” means one element or more than one element.

The terms “comprise,” “include,” and “have,” and the derivatives thereof, are used herein interchangeably as comprehensive, open-ended terms. For example, use of “comprising,” “including,” or “having” means that whatever element is

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comprised, had, or included, is not the only element encompassed by the subject of the clause that contains the verb.

FIGS. 1-3 illustrate an exemplary embodiment of a surgical access port 10 for providing posterior, lateral, or anterior access to the spine. The exemplary port includes a proximal end 12, a distal end 14 spaced apart a distance from the proximal end 12 and a sidewall 16 defining a lumen 18 extending from the proximal end 12 to the distal end 14. In the exemplary embodiment, the lumen 18 has a length sufficient to at least span from a skin incision to proximate a vertebra. The exemplary port 10, in the illustrated embodiment, may include a first opening 30 formed in the sidewall 16 that defines a passageway for medical hardware, such as, for example, surgical instruments and/or implants, from the lumen to external to the port, as discussed in more detail below. The lumen 18 of the exemplary port 10 provides unobstructed access from the proximal end of the lumen 18 to the distal end of the lumen 18 to permit the advancement of instruments and/or implants through the lumen 18.

The size and shape of the exemplary port 10 may vary depending on the intended use of the port 10, for example, the region of the spine, e.g., cervical, thoracic, or lumbar, the approach, e.g., posterior, lateral, or anterior, and the type(s) of implants and instruments desired to be positioned through the lumen 18 of the port 10. In illustrated exemplary embodiments, for example, the port 10 may have a length l sufficient to span from a posterior skin incision to proximate a vertebra. The length l of the port 10 may be varied, for example, depending on whether the port 10 is designed for use in the cervical, thoracic, or lumbar spine. For example, the port 10 may have a length l that allows the proximal end 12 of the port 10 to be positioned outside the patient's body, e.g., proximal to or parallel to the level of the skin, while the distal end 14 of the port 10 is in proximity to or abuts against a posterior surface of a vertebra.

Continuing to refer to FIGS. 1-3, the exemplary port 10 may have a cross-sectional shape and size that varies depending on the intended use of the port 10, for example, the region of the spine, e.g., cervical, thoracic, or lumbar, and the type(s) of implants and instruments desired to be positioned through the lumen 18 of the port 10. In the exemplary embodiment illustrated in FIGS. 1-3, for example, the exemplary port 10 has a circular cross section. In other exemplary embodiments, such as the exemplary port 110 illustrated in FIGS. 4-6, the port 110 may have an elliptical or oval cross-section. One skilled in the art will appreciate that the port 10 may have a cross section that is circular, rectangular, square, elliptical, polygonal or any other shape suitable for providing surgical access to the spine. In the exemplary embodiments illustrated in FIGS. 1-3 and 4-6, the port 10 and the port 100 each have a generally constant cross section, e.g., the size and/or shape of the cross section of the port does not vary along the length l of the cannula. In certain other exemplary embodiments, the cross section of the port may vary in size and shape along the length l of the cannula. For example, the width or diameter of the port may vary along the length of the cannula. In the exemplary embodiments illustrated in FIGS. 1-3 and 4-6 the port 10 and the port 100 each have a continuous cross section in the manner of, for example, a cannula. In certain other embodiments, the port may have a non-continuous cross-section. For example, the port may have a C-shaped cross section or may include one or more longitudinally oriented slots that interrupt the cross section along the length l of the port. In certain exemplary embodiments, the distal end 14 of the port 10 may be sized and shaped to facilitate engagement with the anatomy of the vertebra. For example, the distal end 14 may have a beveled, tapered, and/or angled shape.

In the exemplary embodiment illustrated in FIGS. 1-3, the lumen 18 of the exemplary port 10 may have a diameter d that is sufficient to allow a spinal implant and/or instrument to be introduced therethrough. Examples of spinal implants that may be introduced through the port 10 include spinal fixation elements, such as a plate, rod, or tether, interbody fusion devices, nucleus replacement devices, artificial discs, and fasteners, such as bone anchors. The diameter d of the lumen 18 may be sized to allow any of these implants and associated instruments to be introduced therethrough. In certain exemplary embodiments, the diameter d of the exemplary port 10 may be sized to provide access to a portion of a first vertebra, for example, the pedicle, e.g., for placement of a bone anchor. In certain exemplary embodiments, the diameter d of the exemplary port 10 may be sized to span between a first vertebra and a second vertebra to provide access to the first vertebra, the second vertebra and the disk therebetween.

The exemplary port 10 may be constructed from any material suitable for use in vivo, including metals, such as stainless steel or titanium, polymers, ceramics, or composite materials.

In certain exemplary embodiments, the port 10 may be constructed from a translucent polymer. The outer surface of the sidewall 16 of the exemplary port 10 may be contoured to minimize sharp edges and, thereby, inhibit injury to muscles and tissues surrounding the port 10. In addition, the outer surface of the sidewall 16 of the port 10 may include surface texturing to facilitate holding retracted tissue in place, in particular, away from the distal end of the lumen 18. The surface texturing may be, for example, one or more annular grooves 20 formed in the outer surface of the sidewall 16 of the port 10. In certain embodiments, the surface texturing may be surface roughening, ridges, spiral grooves, and/or materials with a high coefficient of friction. In certain exemplary embodiments, the outer surface of the sidewall 16 of the port 10 is coated with silicon to facilitate holding refracted tissue.

The proximal end 12 of the exemplary port 10 may optionally include a positioning ring 24 that facilitates the positioning of the port 10. The positioning ring 24 may be generally annular in shape and may have an outer diameter that is greater than the diameter of the port 10. The positioning ring 24, in the exemplary port 10, may have a tapered opening 26 that tapers to the diameter of the lumen 16 of the port to facilitate positioning of implants and instruments into the port 10. The positioning ring 24 may include one or more tabs 28 that facilitate connection of the positioning ring 24 and, thus, the port 10, to a clamp, such as a C-arm.

The exemplary port 10 may be configured to hold a light source that illuminates the lumen 18 and/or the distal end 32 of the port 10, for example, during a procedure performed in the port 10. In one exemplary embodiment, the proximal end 12 may include a coupling mechanism, for example, a clamp, for hold one or more light sources, for example, a fiber optic cable or a light tube, that is oriented to illuminate the lumen and the distal end of the port 10. In other exemplary embodiments, one or more light sources, for example, a fiber optic cable or a light tube, may be embedded within the sidewalls 16 of the port 10 to illuminate the lumen 18 and/or the distal end 14 of the port 10.

Continuing to refer to FIGS. 1-3, the exemplary port 10 may include one or more openings 30 formed in the sidewall 16 of the port 10. In the illustrated embodiment, for example, the port 10 includes a single opening 30 formed in the sidewall 16 of the port 10. The opening 30 defines a passageway for medical hardware, for example spinal instruments and implants, between the lumen 18 and the exterior of the port 10. For example, once the port 10 is positioned in proximity

to a surgical site, medical hardware may be advanced subcutaneously from the lumen 18 to external to the port 10, as indicated by arrow A in FIG. 3. Alternatively, medical hardware may be advanced subcutaneously from exterior to the port 10 into the lumen 18 through the passageway, as indicated by arrow A' in FIG. 3.

The size, shape, position, and number of the opening(s) 30 may be varied depending on, for example, the procedure selected and the medical hardware employed. The exemplary ports 10, 110, and 210, illustrated in FIGS. 1-3, 4-6, and 12, respectively, provide examples of ports having various sized, shaped, and positioned opening(s). For example, in the exemplary embodiment illustrated in FIGS. 1-3, the opening 30 may be sized, shaped, and positioned to facilitate delivery of a spinal fixation element, such as a plate, rod, cable, or tether, to a site exterior to the port 10. The opening 30, in the exemplary port 10, is an elongated slot extending proximally from the distal end 14 of the port 10. The opening 30 is oriented generally parallel to the longitudinal axis 22 of the port 10 and defines a passageway that is oriented approximately parallel to the longitudinal axis 22 of the port, as indicated by arrow A in FIG. 3. The opening 30, in the exemplary embodiment, has length $l_{sub.s}$ and a width $w_{sub.s}$ that are selected to allow at least a portion of a fixation element, such as a spinal rod, to be manipulated from within the lumen 18 through the passageway defined by the opening 30. The opening 30 is positioned at the distal end 14 of the port 10 and has an open, i.e., unobstructed, distal end 32.

FIGS. 4-6 illustrate an exemplary embodiment of a surgical access port 110 having two openings 130A, 130B formed in a sidewall 116 of the port 110 to facilitate passage of medical hardware between the lumen 118 of the port 110 and the exterior of the port 110. The size, shape, position, and number of the openings 130A,B may be varied depending on, for example, the procedure selected and the medical hardware employed. For example, the openings 130A,B may be sized, shaped, and positioned to facilitate delivery of a spinal fixation element, such as a plate, rod, cable, or tether, to a site exterior to the port 110 or to receive a spinal fixation element delivered to the lumen 118 of the port 110. The openings 130A,B in the exemplary port 110, are elongated slots extending proximally from the distal end 114 of the port 110. The openings 130A,B, in the illustrated embodiment, are oriented generally parallel to the longitudinal axis 122 of the port 110. The openings 130A, 130B are positioned generally opposite from each other, as illustrated in FIG. 6, and each opening 130A,B defines a passageway oriented approximately perpendicular to the longitudinal axis 122 of the port 110 for the passage of medical hardware, such as instruments or implants, out of the lumen 118 of the port 110, as indicated by arrows B, and/or into the lumen 118 of the port, as indicated by arrows B'. In the illustrated embodiment, for example, the length $l_{sub.sa}$ of the first opening 130A is less than the length $l_{sub.sb}$ of second opening 130B. In other exemplary embodiments, the length $l_{sub.sa}$ of the first opening 130A may be equal to the length $l_{sub.sb}$ of second opening 130B.

FIG. 12 illustrates another exemplary embodiment of a surgical access port 210 having an opening 230 formed in a sidewall of the port 210. The opening 230 in the exemplary port 210 is an elongated slot that is oriented approximately parallel to the longitudinal axis 222 of the port 210 and is positioned between the distal end 214 and the proximal end 212 of the port 210. Unlike the exemplary ports 10, 110, described above, the opening 212 is not open at the distal end thereof. The position of the opening 230, as well as the size, shape, and number of opening(s) may be varied depending on, for example, the procedure selected and the medical hardware.

ware employed. For example, the opening **230** in the illustrated embodiment is positioned proximate the distal end **214** of the port **210**. In other exemplary embodiments, the opening **230** may be positioned proximate the proximal end of the port **210**.

FIG. **13** illustrates an exemplary embodiment of a surgical access port **910** having a plurality of openings **930A**, **930B** formed in the sidewall **916** of the port **910**. In the illustrated exemplary embodiment, the port **910** includes a distal opening **930A** extending proximally from the distal end **914** of the port **910** and a proximal opening **930B** extending distally from the proximal end **912** of the port **910**. In the illustrated exemplary embodiment, the distal opening **930A** and the proximal opening **930B** are opposed from one another and overlap along at least a portion of the longitudinal axis **922** of the port **910**.

One skilled in the art will appreciate that the size, shape, position, orientation, and number of opening(s) is not limited to the embodiments described above. For example, the opening(s) may be circular, square, oval, or polygonal in shape and any number of openings may be employed.

In certain exemplary embodiments, the port may include indicia for indicating the location of the opening(s) on the port. For example, the proximal end **12** of the exemplary port **10** illustrated in FIGS. **1-3** may include one or more raised ridges **32** that indicate the position and orientation of the opening **30** in the sidewall **16** of the port **10**. In the illustrated embodiment, a first ridge **32A** is circumferentially aligned with the opening **30** and the second ridge **32B** is diametrically opposed to the opening **30**. In alternative embodiments, indicia for indicating the position of the opening in the sidewall of the slot may be a groove or mark on the proximal end and/or the sidewall or within the lumen of the port.

The surgical access ports disclosed herein may be employed to provide surgical access to the spinal anatomy. In one exemplary embodiment, a surgical access port, such as any of the exemplary ports described above, may be inserted, for example through an incision, into proximity to a first vertebra of the spine. For example, the distal end **14** of the surgical access port **10** illustrated in FIGS. **1-3** may be advanced into proximity to the first vertebra to define a first pathway to the first vertebra through the lumen **18** of the surgical access port **10**. An instrument and/or implant may be advanced through the lumen **18** of the port **10** into proximity to the first vertebra to perform a procedure at the first vertebra or to perform a procedure at a location proximal to the first vertebra. Such procedures may be performed by manipulating an instrument and/or implant within the lumen **18** of the port **10** and/or by manipulating the instrument and/or implant through an opening **30** in the sidewall of the port **10**. For example, an instrument and/or an implant may be advanced through the opening **30** to perform a procedure at the first vertebra or a position proximate the first vertebra, such as at a second vertebra that is adjacent to the first vertebra. Exemplary procedures include laminotomy, facetectomy, foraminotomy, nerve root retraction, discectomy, and/or positioning of a spinal implant such as a spinal fixation element, such as a plate, rod, or tether, an interbody fusion device, a nucleus replacement device, an artificial disc, and a fastener, such as a bone anchor.

In certain exemplary embodiments, the distal end of a surgical access port, such as any of the exemplary ports described above, may be moved between two or more locations to perform procedures at multiple sites. For example, the distal end **14** of the exemplary port **10** may be advanced, e.g., through an incision, into proximity to a first and second vertebrae. The proximal end **12** of the port **10** may be manipu-

lated to move the distal end **14** into alignment with at least a portion of the first vertebra by, for example, angling the proximal end **12** relative to the skin incision in a procedure generally referred to as "wandering." A procedure may be performed at the first vertebra, such as, for example, placement of a first bone anchor in the first vertebra. The proximal end **12** of the port **10** may be manipulated to move the distal end **14** into alignment with at least a portion of the second vertebra and a procedure may be performed at the second vertebra, such as, for example, placement of a second bone anchor in the second vertebra. A fixation element, such as a spinal rod, may be coupled to the first and second bone anchors using the surgical access port. For example, a first end of the fixation element may be positioned in the port and advanced through the lumen **16** to the opening **30**. The first end of the fixation element may be advanced subcutaneously through the opening **30** toward the first vertebra. The fixation element may be coupled to the second anchor by, for example, delivering a closure mechanism, such as a set screw or cap, through the port **10** to the second anchor. The proximal end **12** of the port **10** may be manipulated to move the distal end **14** into alignment with the first vertebra. During movement of the distal end **14** of the port **10** to the first vertebra, the opening may be aligned with the fixation element such that the distal end **14** moves along the fixation element toward the first vertebra. Once the distal end **14** of the port **10** is aligned with the first end of the fixation element may be positioned relative to the first anchor and the fixation element may be coupled to the first anchor.

The fixation element may be advanced within the lumen of the port and subcutaneously through the opening(s) in the port using any conventional instrument for manipulating a spinal fixation element. In certain exemplary embodiments, the fixation element may be advanced through the lumen of the port in orientation substantially parallel to the longitudinal axis of the port. The fixation element may be manipulated through the opening(s) in the port to an orientation that is angled with respect to the longitudinal axis of the port. In certain embodiments, the fixation element may be oriented substantially perpendicular to the longitudinal axis of the port. Exemplary instruments for manipulating a spinal fixation element between two or more orientations are disclosed in U.S. patent application Ser. No. 10/737,166, filed Dec. 16, 2004; U.S. patent application Ser. No. 10/737,538, filed Dec. 16, 2004; and U.S. Patent Application Ser. No. 60/542,548, filed Apr. 27, 2004, each of the aforementioned patent applications are incorporated herein by reference.

In certain exemplary embodiments, two or more surgical access ports, such as any of the exemplary ports described above, may be employed to provide access to multiple sites proximate the spine. For example, two surgical access ports may be employed to facilitate subcutaneous placement of a spinal fixation element between two or more vertebrae. In one exemplary embodiment, for example, a first port, such as exemplary port **10**, may be inserted to define a first pathway to a first vertebra. A first bone anchor may be advanced through the lumen **16** of the first port **10** to the first vertebra. A second port, such as exemplary port **10**, may be inserted to define a second pathway to a second vertebra, which, for example, may be adjacent the first vertebra. A second bone anchor may be advanced through the lumen of the second port to the second vertebra. A spinal fixation element, for example, a spinal rod, may be positioned in the lumen of the first port. An end of the spinal fixation element may be advanced through an opening **30** of the first port **10** and advanced subcutaneously to an opening **30** in the second port. The spinal fixation element may be coupled to the first anchor by delivering a

closure mechanism through the lumen **16** of the first port and to the second anchor by delivering a closure mechanism to the second anchor through the second port.

FIGS. 7-11 schematically illustrate an exemplary method of minimally invasive surgery that provides for the placement of multiple bone anchors and a fixation element on one or both sides of a patient's spine. The exemplary method may be employed to stabilize and align two or more bone segments, in particular, two vertebrae (VB.sub.1, VB.sub.2), in a minimally invasive manner that reduces trauma to adjacent tissue.

Referring to FIG. 7, the exemplary method may comprise making a first incision in a patient and positioning a first surgical access port **310**, such as an exemplary surgical access port described above, in the first incision. In the illustrated embodiment, the first port **310** is analogous in construction to the exemplary surgical access port illustrated in FIGS. 4-6 and described above. The distal end **314** of the port **310** is advanced into proximity to a first vertebra VB.sub.1 and the lumen **316** of the first port **310** defines a first pathway from the incision to the first vertebra VB.sub.1.

The first incision may be a minimally invasive incision made in the patient's skin that is expanded, for example, by retraction and/or dilation, to create a pathway from the first incision to the proximate the first vertebra VB.sub.1. The first incision **14** may be expanded to create the pathway in any conventional manner. In certain embodiments, for example, the first incision may be expanded by dilation to the desired size, shape, and orientation. For example, the first incision may be sequentially dilated using a plurality of dilators to create the pathway to the first vertebra. Exemplary methods and instruments for serial dilation are described in commonly owned U.S. Pat. No. 6,159,179, entitled Cannula and Sizing and Insertion Method; U.S. patent application Ser. No. 10/024,221, filed Oct. 30, 2001, entitled Non-Cannulated Dilators; and U.S. patent application Ser. No. 10/021,809, filed Oct. 30, 2001, entitled Configured and Sized Cannulas, each of which is incorporated herein by reference. In other embodiments, a single dilator may be employed to expand the incision. Once dilation is concluded, the first port **310** may be positioned into the dilated first incision to define a first passageway to the vertebra. Alternatively, a retractor may be inserted into the dilated first incision to further expand the first incision and then the first port may be positioned in the first incision.

In certain exemplary embodiments, the first incision may be expanded by inserting one or more retractors into the incision and expanding the incision to the desired size, shape, and orientation by expanding the retractor accordingly. Any type of conventional retractor or retractors may be employed to expand the first incision. For example, suitable retractors are described in commonly owned U.S. patent application Ser. No. 10/815,182, filed Mar. 31, 2004, entitled Telescoping Blade Assemblies and Instruments for Adjusting an Adjustable Blade; U.S. Provisional Patent Application Ser. No. 60/530,655, filed Dec. 18, 2003, entitled Surgical Retractor Systems, Illuminated Cannula and Methods of Use; and U.S. patent application Ser. No. 10/808,687, entitled Surgical Retractor Positioning Device, each of which are incorporated herein by reference.

In certain exemplary embodiments, the first incision may be expanded to create a pathway by an intermuscular procedure that includes locating a muscle plane separating two muscles and separating the muscles at the muscle plane to create the first pathway. For example, in certain exemplary methods, the intermuscular plane separating the multifidus and longissimus muscles may be located through the first incision. The multifidus and longissimus muscles may be

separated at the muscle plane by blunt dissection, for example, by inserting a finger or an instrument, such as a retractor, through the muscle plane and advancing the finger or instrument to the vertebra to create the pathway to the vertebra. Intermuscular procedures are described in detailed in U.S. Pat. No. 6,692,434, entitled Method and Device for Retractor for Microsurgical Intermuscular Lumbar Arthrodesis; U.S. patent application Ser. No. 10/060,905, filed Jan. 29, 2002, entitled Retractor and Method for Spinal Pedicle Screw Placement; and New Uses and Refinements of the Paraspinal Approach to the Lumbar Spine, L. L. Wiltse and C. W. Spencer, Spine, Vol. 13, No. 6, Nov. 6, 1988, each of which is incorporated herein by reference.

The first incision may be a percutaneous skin incision that has a shape and extent that is less than, equal to, or slightly greater than, the extent of the instruments and implants being inserted thereto. In certain exemplary embodiments, for example, the incision may be a stab incision that is expanded to facilitate positioning of the first port **310** therethrough.

Continuing to refer to FIG. 7, a first anchor **300** may be advanced through the first pathway defined by the lumen **316** of the first port **310** to an anchor site on the first vertebra VB.sub.1. The first bone anchor **300** may be any type of conventional bone anchor, including, for example, a mono-axial or polyaxial bone screw, a bolt, or a hook. The first bone anchor **300** may be implanted into any portion of the first vertebra VB.sub.1 respectively, in any conventional manner through the first incision. In the illustrated embodiment, the first bone anchor **300** is implanted into a first pedicle P.sub.1 of the first vertebra VB.sub.1.

A second surgical access port **410** may be inserted through a second incision to define a second pathway from the second incision to a second vertebra VB.sub.2. In the illustrated embodiment, the second port **410** is analogous in construction to the first port except the second port **410** has a single opening **430** and the first port **310** has two openings **330A**, **330B**. The opening **430** in the second port may be aligned with at least one of the openings **330A**, **330B** in the first port **310** by, for example, rotating one or both of the ports. Alignment indicia on the proximal end of the ports may be employed to facilitate alignment of the openings. In the illustrated embodiment, the opening **430** in the second port **410** is aligned with the opening **330A** of the first port **310**.

The second incision may be expanded to create a pathway to the second vertebra VB.sub.2 in a manner analogous to the first incision described above. The second incision may be a percutaneous skin incision in a manner analogous to the first incision.

Continuing to refer to FIG. 7, a second bone anchor **302**, e.g., a polyaxial bone screw analogous to the first bone anchor, may be advanced through the second pathway defined by the lumen **416** of the second port **410** to a second anchor site on the second vertebra VB.sub.2. The second bone anchor **302** may be implanted into any portion of the second vertebra VB.sub.2 respectively, in any conventional manner through the second incision. In the illustrated embodiment, the second bone anchor **302** is implanted into a second pedicle P.sub.2 of the second vertebra VB.sub.2.

A spinal fixation element, for example, a spinal rod, may be positioned in the first port **310** and advanced subcutaneously through the opening **330A** and the opening **430** to the second anchor **302**. In the exemplary method, a first instrument **500** may be employed for creating a subcutaneous pathway between the first port **310** and the second port **410** to facilitate advancement of the spinal fixation element to the second anchor **302**. The exemplary first instrument **500**, as illustrated in FIG. 7, includes a proximal handle **502**, a shaft **504** having

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a longitudinal axis **506**, and a distal tip **508** that is oriented at an angle to the shaft **504** and is configured to dissect tissue. The shaft **504** of the exemplary instrument is preferably sized to fit through the lumen of the first port **310**. The distal tip **508** may be oriented at an angle greater than or equal to approximately 45.degree. to the longitudinal axis **506** of the shaft **500**, and, in the illustrated embodiment, is oriented approximately perpendicular to the longitudinal axis **506** of the shaft **500**, although one skilled in the art will appreciate that other angles suitable for creating a subcutaneous pathway may be utilized. The distal tip **508**, in the illustrated embodiment, terminates at a tip **510** suitable for dissecting tissue. The length of the distal tip **508**, indicated by arrow **512** in FIG. 7, may be varied depending on the procedure and the anatomy. In the illustrated embodiment, for example, the length of the distal tip is selected to span the distance between the distal end **314** of the first port **310** and the distal end of the second port **410**. In certain exemplary embodiments, the tip **510** of the instrument **500** may be sized to interface with a bone anchor positioned in the first port **310** and/or the second port **410**. For example, the tip **510** of the instrument **500** may be sized to seat within the spinal fixation element receiving portion of the bone anchor. In the case of a polyaxial bone screw, for example, the tip **510** of the instrument **500** may be sized to seat within the spinal rod receiving slot of the polyaxial bone screw.

Continuing to refer to FIG. 7, the first instrument **500** may be manipulated to advance the distal tip **508** through the opening **330A** in the first port **310** to create a subcutaneous pathway between the opening **330A** in the first port **310** and the opening **430** in the second port **410**.

In certain alternative embodiments, the spinal fixation element may have a tip configured to create a subcutaneous pathway. For example, the fixation element may be a spinal rod having a tip suitable for tissue dissection. Advancement of the spinal rod to the second anchor may create the subcutaneous pathway between the first port **310** and the second port **410**.

In certain exemplary embodiments, including the illustrated embodiment, a second instrument **600** may be used in cooperation with the first instrument **500** to facilitate the creation of a subcutaneous pathway between the distal end **314** of the first port **310** and the distal end **414** of the second port **410**. The exemplary second instrument **600**, as illustrated in FIGS. 7-10, includes a proximal handle **602**, a shaft **604** having a longitudinal axis **606**, and a distal tip **608** oriented at an angle to the longitudinal axis **606** of the shaft **604**. The shaft **604** of the exemplary second instrument **600** is preferably sized to fit through the lumen **416** of the second port **610**. The distal tip **608** of the second instrument **600**, in the illustrated embodiment, is oriented approximately perpendicular to the longitudinal axis **606** of the shaft **600**, although one skilled in the art will appreciate that other angles suitable for creating a subcutaneous pathway may be utilized. The distal tip **608** may be sized to receive at least a portion of the distal tip **508** of the first instrument **500**. For example, in the exemplary embodiment, the distal tip **608** of the second instrument **600** may be generally arcuate in cross-section and may include a proximal surface **610** for receiving the distal tip **508** of the first instrument **500**. The proximal surface **610** may be complementary in size and shape to the distal tip **508** of the first instrument **500** to facilitate alignment of the distal tip **508** of the first instrument **500** and the distal tip **608** of the second instrument **600**. For example, the proximal surface **610** may have a curvature analogous to the curvature of the distal tip **508** of the first instrument **500**. In certain exemplary embodiments, the distal tip **508** of the first instrument **500** and the

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distal tip **608** of the second instrument **600** may be coaxially aligned when engaged with one another. One skilled in the art will appreciate the distal tip **608** of the second instrument **600** may have other configurations suitable for receiving the distal tip **508** of the first instrument **500**. For example, the distal tip **608** of the second instrument **600** may be generally cylindrical in shape, having for example, a generally circular cross section, for receiving the distal tip **508** of the first instrument **500** in a telescoping relationship. In certain exemplary embodiments, the tip **610** of the instrument **600** may be sized to interface with a bone anchor positioned in the first port **310** and/or the second port **410**. For example, the tip **610** of the instrument **600** may be sized to seat within the spinal fixation element receiving portion of the bone anchor. In the case of a polyaxial bone screw, for example, the tip **610** of the instrument **600** may be sized to seat within the spinal rod receiving slot of the polyaxial bone screw.

One skilled in the art will appreciate that use of the first instrument **500** and/or the second instrument **600** is optional. The first instrument **500** may be employed independent of the second instrument **600** to create a subcutaneous pathway between the distal end **314** of the first port **310** and the distal end **414** of the second port **410**. As discussed above, in certain exemplary embodiments, the subcutaneous pathway may be created without instruments by, for example, advancement of the spinal fixation element from the first port to the second port.

In the exemplary method, the distal tip **508** of the first instrument **500** is advanced to the opening **430** in the second port **410** and into the distal tip **608** of the second instrument **600**, thereby creating the subcutaneous pathway. As illustrated in FIG. 9, the first instrument **500** and the second instrument **600** may be cooperatively manipulated to facilitate creation and expansion of the subcutaneous pathway between the distal end **314** of the first port **310** and the distal end **414** of the second port **410**. For example, the proximal handle **502** of the first instrument **500** and the proximal handle **602** of the second instrument **600** may be moved in unison to cause the distal tips **508**, **608** to move in unison between the distal ends of the first and second ports **310**, **410**.

Referring to FIG. 10, a spinal fixation element, for example a spinal rod **700**, may be advanced subcutaneously to the second anchor **302** using an instrument for manipulating a spinal fixation element, as described above. In the illustrated embodiment, an exemplary spinal rod manipulating instrument **800** includes a proximal handle **802**, a shaft **804**, and a distal end **806** that may be pivotally connected at a pivot point **810** to a first end **702** of the exemplary spinal rod **700**. The exemplary rod manipulating instrument **800** allows the rod **700** to be positioned in the first port **310** in an orientation approximately parallel to the longitudinal axis of the first port **310** and to be pivoted to a non-parallel orientation to facilitate advancement of the rod **700** through a distal opening **330** in the port **310**. In the exemplary embodiment, the rod **70** may be pivoted to an orientation that is substantially perpendicular to the longitudinal axis of the first port **310** to allow the second end **704** of the rod **700** to be advanced through the opening **330A** and subcutaneously to the second port **410**, as illustrated in FIG. 10. In the exemplary embodiment, the port **310** is provided with two opposed openings **330 A,B** to facilitate transition of the rod **700** to an orientation suitable for subcutaneous advancement of the rod. For example, the opening **330A** allows the first end **702** of the rod **700** to be pivoted to a non-parallel orientation, as illustrated by arrow P in FIG. 10. The manipulating instrument **800** may be employed to facilitate subcutaneous advancement of the rod **700** to the second port **410**.

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In certain exemplary embodiments, the second instrument 600 also may be employed to facilitate subcutaneous advancement of the rod 700 to the second port 410, as illustrated in FIG. 10. The distal tip 608 of the second instrument 600 may receive a portion of the rod 700, for example, the second end 704 of the rod 700, and may guide the rod 700 along the subcutaneous pathway to the second port 410. One skilled in the art will appreciate that use of the second instrument 600 is optional and that in certain exemplary embodiments the rod 700, or other fixation element, may be advanced to the second port 410 independent of an instrument positioned in the second port 410.

Once the spinal fixation element, e.g., rod 700, is advanced to the second port 410, the fixation element may be coupled to the first anchor 300 and the second anchor 302. For example, a closure mechanism 304B may be advanced through the first port 310 to the first anchor 300 and a closure mechanism 304B may be advanced through the second port 410 to the second anchor 302, as illustrated in FIG. 11. The closure mechanisms may be coupled to the bone anchors to secure the spinal fixation element to the bone anchors.

In certain exemplary embodiments, the disk space D between the first and second vertebrae VB.sub.1, VB.sub.2 may be accessed through the first port 310 and/or the second port 410. For example, the distal end 314 of the first port 310 and/or the distal 414 end of the second port 410 may be moved into alignment with the disk space. In certain exemplary embodiments, the first port 310 and the second port 410 may be selected to have a size sufficient to provide access to a vertebra and the adjacent disk space. Accessing the disk space allows one or more procedures to be performed at the disk space. For example, all or a portion of the disk material may be removed from the disk space D. In certain embodiments, an interbody fusion device, including, for example, bone graft or a cage, may be placed in the disk space D to promote fusion of the first and second vertebrae VB.sub.1, VB.sub.2. In certain embodiments, an artificial disk may be placed in the disk space D.

In certain exemplary embodiments, the disk space D between the first and second vertebrae VB.sub.1, VB.sub.2 may be accessed through a separate incision, e.g., a third, incision, rather than the first incision through which the first port 310 is positioned and the second incision through which the second port 410 is positioned.

One skilled in the art will appreciate that the order of the steps of the exemplary method described in connection with FIGS. 7-11 is merely exemplary and the steps may be carried out in one or more different orders. For example, in certain exemplary embodiments, the subcutaneous pathway between the first port and the second port may be created before advancing the first anchor through the first port and before advancing the second anchor through the second port. In other exemplary embodiments, the subcutaneous pathway may be created after advancing the first anchor through the first port and before advancing the second anchor through the second port. In other exemplary embodiments, the first port and the second port may be placed before advancement of the first anchor and the second anchor through the ports.

While methods and instruments of the present invention have been particularly shown and described with reference to the exemplary embodiments thereof, those of ordinary skill in the art will understand that various changes may be made in the form and details herein without departing from the spirit and scope of the present invention. Those of ordinary skill in the art will recognize or be able to ascertain many equivalents to the exemplary embodiments described specifically herein by using no more than routine experimentation. Such equivalents

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are intended to be encompassed by the scope of the present invention and the appended claims.

What is claimed:

1. A system for minimally invasive spine surgery comprising:
 - a plurality of bone anchors configured for implantation in a vertebra;
 - a spinal rod configured to connect one bone anchor of the plurality of bone anchors implanted in a first vertebra with a second bone anchor of the plurality of bone anchors implanted in a second vertebra;
 - a plurality of dilators of varying lengths and diameters;
 - a first surgical access port comprising a proximal end, a distal end spaced apart a distance from the proximal end, and a sidewall defining a lumen extending from the proximal end to the distal end, the lumen having a length sufficient to at least span from a skin incision to approximate a vertebra and a diameter greater than the diameters of the plurality of dilators, the first surgical access port having a first opening formed in the sidewall, the first opening defining a passageway for medical hardware from the lumen to external to the first surgical access port;
 - a second surgical access port comprising a proximal end, a distal end spaced apart a distance from the proximal end, and a sidewall defining a lumen extending from the proximal end to the distal end, the lumen having a length sufficient to at least span from a skin incision to approximate a vertebra and a diameter greater than the diameters of the plurality of dilators, the second surgical access port having a first opening formed in the sidewall, the first opening defining a passageway for medical hardware from the lumen to external to the second surgical access port;
 - a first instrument for creating a subcutaneous pathway from the opening in the first surgical access port to the opening in the second surgical access port, the first instrument having a distal end sized to pass through the opening in first surgical access port and extend from the subcutaneously from a first vertebra to a second vertebra, and
 - a second instrument having a distal end sized to pass through the opening in the second surgical access port and configured to engage the distal end of the first instrument.
2. The system of claim 1, wherein the second instrument further comprises a proximal handle, a shaft having a longitudinal axis, the shaft being sized to fit through the lumen of the second surgical access port and wherein the distal end of the second instrument is oriented at angle to the shaft and is sized to receive at least a portion of the distal end of the first instrument therein.
3. The system of claim 1, wherein the spinal rod has a tip configured to dissect tissue.
4. The system of claim 1, wherein the first instrument comprises a proximal handle, a shaft having a longitudinal axis, the shaft being sized to fit through the lumen of the port and wherein the distal end is oriented at angle to the shaft.
5. The system of claim 4, wherein the distal end is oriented approximately perpendicular to the longitudinal axis of the shaft.
6. The system of claim 4, wherein the distal end is sharpened sufficiently to dissect tissue.
7. A system for minimally invasive spine surgery comprising:
 - a plurality of bone anchors configured for implantation in a vertebra;

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a spinal rod configured to connect one bone anchor of the plurality of bone anchors implanted in a first vertebra with a second bone anchor of the plurality of bone anchors implanted in a second vertebra;

a plurality of dilators of varying lengths and diameters; 5

a first surgical access port comprising a proximal end, a distal end spaced apart a distance from the proximal end, and a sidewall defining a lumen extending from the proximal end to the distal end, the lumen having a length sufficient to at least span from a skin incision to proximate a vertebra and a diameter greater than the diameters of the plurality of dilators, the first surgical access port having a first opening formed in the sidewall, the first opening defining a passageway for medical hardware from the lumen to external to the first surgical access port; 15

a second surgical access port comprising a proximal end, a distal end spaced apart a distance from the proximal end, and a sidewall defining a lumen extending from the proximal end to the distal end, the lumen having a length sufficient to at least span from a skin incision to proximate a vertebra and a diameter greater than the diameters of the plurality of dilators, the second surgical access port having a first opening formed in the sidewall, the first opening defining a passageway for medical hardware from the lumen to external to the second surgical access port; 20

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a first instrument for creating a subcutaneous pathway from the opening in the first surgical access port to the opening in the second surgical access port, the first instrument having a distal end sized to pass through the opening in first surgical access port and extend from the subcutaneously from a first vertebra to a second vertebra, the first instrument having a proximal handle, a shaft having a longitudinal axis, the shaft being sized to fit through the lumen of the port and wherein the distal end is oriented at angle to the shaft; and

a second instrument having a distal end sized to pass through the opening in the second surgical access port and configured to engage the distal end of the first instrument, the second instrument having a proximal handle, a shaft having a longitudinal axis, the shaft being sized to fit through the lumen of the second surgical access port and wherein the distal end of the second instrument is oriented at angle to the shaft and is sized to receive at least a portion of the distal end of the first instrument therein.

8. The system of claim 7, wherein the distal end is oriented approximately perpendicular to the longitudinal axis of the shaft.

9. The system of claim 7, wherein the distal end is sharpened sufficiently to dissect tissue.

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